COMMISSION OF THE EUROPEAN COMMUNITIES

COM(78) 748 final
Brussels, 3 January 1979

Proposal for a
Council Regulation

introducing Community measures for the
prevention of classicla swine fever

(submitted to the Council by the Commission)

EXPLANATORY MEMORANDUM

Classical swine fever is a serious contagious disease of pigs which in its acute form has a high mortality rate and in its other forms results in diminished profits owing to abortions, sterility and reduced growth rates.

The approach to the disease, particularly the action taken to deal with outbreaks, varies considerably from one Member State to another, and this is a barrier to intra-Community trade.

The purpose of this regulation is to give the Community an efficient harmonized system of action for fighting classical swine fever in the Community. It is particularly necessary to eliminate sources of the disease by slaughtering animals that are either infected or are potential transmitters of it and by applying rigorous disinfection and control measures to holdings suspected of being contaminated. It is indispensable, in order to eliminate all risk of epizootics, that rapid, precise and harmonized diagnostic methods be used by the responsible national laboratories.

This regulation is the basis of a Community operation for the establishment and maintenance of uniform health standards in respect of classical swine fever.

COUNCIL REGULATION

introducing Community measures for the prevention of classical swine fever

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas one of the Community's tasks in the veterinary field is to improve the health of livestock, thereby increasing the profitability of stock farming;

Whereas, moreover, such action should help to remove those remaining barriers to trade between Member States in live animals and fresh meat which are caused by differences in their respective animal health situations;

Whereas an outbreak of classical swine fever can take on epizootic proportions, causing mortality and disturbances on a scale which threatens the profitability of pig farming as a whole;

Whereas provisions must be adopted as soon as there is suspicion of the disease so that immediate and effective action can be taken as soon as it is confirmed;

Whereas it is necessary to prevent any spread of the disease if an outbreak occurs, by carefully monitoring movements of animals, the use of products liable to be contaminated and vaccination;

Whereas the methods of diagnosing the disease in all its forms under the auspices of the laboratories responsible and the preparation of vaccine must be harmonized;

Whereas common measures for the prevention of classical swine fever form a basis for maintaining a uniform standard of animal health and whereas to that end a procedure should be laid down to establish close cooperation between the Member States and the Commission,

HAS ADOPTED THIS REGULATION :

Article 1

This Regulation introduces Community measures for the prevention of classical swine fever.

Article 2

For the purposes of this Regulation the following definitions shall apply :

a) holding : means any establishment (agricultural or other), situated in the territory of a Member State, in which animals of the porcine species are kept or bred;

b) slaughter pig : means a porcine animal which is intended to be brought immediately to a slaughterhouse for slaughter;

c) fattening pig : means a porcine animal fattened and intended for slaughter at the end of the fattening period with a view to meat production;

d) breeding pig : means a male or female porcine animal intended or used for reproduction with a view to multiplication of the species;

e) pig suspected of being infected with swine fever : means any pig showing clinical signs or post-mortem lesions or reactions to laboratory tests carried out according to Article 11, indicating the possible presence of swine fever;

f) pig infected with swine fever : means any pig
- in which clinical symptoms or post-mortem lesions of swine fever have been officially confirmed or
- in which the presence of this disease has been officially confirmed as the result of a laboratory examination carried out in accordance with Article 11;

g) official veterinarian : means the veterinarian designated by the competent central authority of the Member State;

h) swill : means waste from kitchens, restaurants or industries using meat.

Article 3

The suspicion or existence of swine fever must be notified immediately to the competent authority.

Article 4

1. Where a holding contains one or more pigs suspected of being infected with swine fever, the official veterinarian shall immediately set in motion official means of investigation aimed at confirming or disproving the presence of the said disease.

   From the moment when suspicion is notified the competent authority shall order that :

   - the holding be placed under official surveillance;
   - all the pigs in the various categories on the holding shall be counted and a list compiled of the pigs already dead or likely to be infected in each category; this must also include pigs born during the period of suspicion;
   - all the pigs on the holding shall remain in isolation in their living quarters;
   - no pigs may enter or leave the holding; the competent authority may, if necessary, prohibit animals of other species from leaving the holding;
   - no pigmeat may leave the holding, except where accompanied by an authorizati from the competent authority;
   - no dead pigs may leave except where accompanied by an authorization from the competent authority;
   - no animal feed, utensils, materials or waste may leave the holding, except where accompanied by an authorization from the competent authority;
   - the entry of persons to the holding shall be subject to authorization by the competent authority;
   - the entry of vehicles to the holding shall be subject to authorization by the competent authority;
   - appropriate means of disinfection must be used at the entrance and exits of buildings housing pigs and of the holding itself;
   - an epizootiological enquiry shall be carried out in accordance with Articles 7 and 8.

2. The measures provided for in paragraph 1 shall not be lifted until the suspicion of swine fever has been officially ruled out.

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Article 5

In cases where the presence of swine fever is officially confirmed, the competent authority shall prescribe, in addition to the measures listed in Article 4 (1), the application of the following measures :

- all pigs on the holding shall be slaughtered without delay under official control and in such a way that there is no risk of the swine fever virus spreading during transport and slaughter;
- after slaughter of the pigs mentioned above, all carcases must be destroyed under official control in such a way that there is no risk of the swine fever virus spreading;
- meat of pigs slaughtered on the premises during the period between the probable introduction of disease to the holding and the taking of official measures and stored on the holding shall be destroyed under official control in such a way as to prevent the spread of the swine fever virus;
- pigs having died on the premises shall also be destroyed under official control in such a way as to prevent the spread of the swine fever virus;
- all substances and waste likely to be contaminated, such as feedingstuffs, shall be subjected to a treatment ensuring the destruction of any swine fever virus present; this treatment must be carried out in accordance with the instructions of the official veterinarian;
- after the pigs have been disposed of, the buildings used for housing the pigs, the vehicles used for transporting them and all equipment likely to be contaminated shall be cleaned and disinfected in accordance with the provisions of Article 10;
- the reintroduction of pigs to the holding may not take place until at least 15 days after completion of the cleaning and disinfection operations carried out in accordance with Article 10;
- an epizootiological enquiry shall be carried out in accordance with the provisions of Articles 7 and 8.

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Article 6

1. In order that the fattening of pigs may be completed the Member States may, by way of derogation from the first and second indents of Article 5, postpone the slaughter of certain of the pigs on an infected holding, or refrain from destroying their meat, provided that:

   - the structure and size of the holding are such that each pig unit is housed, kept and fed completely separately;
   - the pigs whose slaughter is postponed are healthy and housed in buildings or blocks apart from that or those containing pigs infected with swine fever, with no direct or indirect contact with the latter, including during the incubation period of the disease;
   - the pigs remain in their living quarters, where they shall be isolated; they may only be moved from the holding to a slaughterhouse under official supervision for the purpose of immediate slaughter;
   - the pigs whose slaughter is postponed are marked in an indelible manner;
   - slaughter of all the pigs takes place within a period of not more than three months from the day when the disease was officially confirmed;
   - meat originating from these pigs is used in such a way that there is no risk of the swine fever virus spreading;
   - the holding remains subject to the other measures laid down in Articles 4 and 5 until the slaughter of all pigs in the herd and the completion of cleaning and disinfection operations in accordance with the provisions of Article 10;
   - the reintroduction of pigs to the holding does not take place until at least 15 days after completion of the cleaning and disinfection, carried out in accordance with the provisions of Article 10, of all the pigs' living quarters.

2. If the disease is officially confirmed among pigs in a unit which is accorded a derogation pursuant to paragraph 1, this unit at least shall be treated pursuant to the first and second indents of Article 5.

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Article 7

The epizootiological enquiry shall deal with:

- the length of time during which swine fever may have existed on the holding before the disease was officially confirmed;
- the possible origin of swine fever on the holding and the identification of other holdings on which there are pigs which may have become infected from the same source;
- the movement of persons, vehicles, pigs, carcases, meat or material likely to have transported the virus from the holding.

Article 8

(a) Where the official veterinarian finds, or considers on the basis of confirmed data, that swine fever could have been introduced from another holding on to the holding referred to in Article 4, or from the latter holding on to another holding, as a result of the movement of persons, pigs or vehicles or in any other way, those other holdings shall be placed under official surveillance.

The official surveillance, the purpose of which shall be to detect immediately any suspicion of swine fever, count animals and monitor their movements and, where appropriate, implement some or all of the measures provided for in Article 4(1), shall be lifted if the suspicion of swine fever in respect of the holding referred to in Article 4 is officially ruled out.

(b) Where the official veterinarian finds, or considers on the basis of confirmed data, that swine fever could have been introduced on to the holding referred to in Article 5 from another holding as a result of the movement of persons, pigs or vehicles or in any other way, that other holding shall be subject to the provisions of Article 4.

Where the official veterinarian finds, or considers on the basis of confirmed data, that swine fever could have been introduced on to the holding referred to in Article 5 from another holding as a result of the movement of persons, pigs or vehicles or in any other way, that other holding shall be placed under official surveillance.

The official surveillance, the purpose of which shall be to detect immediately any suspicion of swine fever, count animals and monitor their movements and, where appropriate, implement some or all of the measures provided for in Article 4(1), shall be maintained for at least 30 days following the date on which, according to estimates, the disease could have been introduced.

2. When a holding has been subjected to the provisions of paragraph 1(a) and the second subparagraph of paragraph 1(b), the competent authority may authorize the movement from the holding of pigs other than those which led to the imposition of the said measures, for transport directly to a slaughterhouse under official supervision for the purpose of immediate slaughter.

   Prior to granting such authorization, the official veterinarian must have carr out an examination of the pig herd and confirmed that none of the pigs is suspected of being infected with swine fever.

3. The competent authority may, where it considers that conditions permit, limit the measures provided for in paragraph 1(a) and the second subparagraph of paragraph 1(b) to a part of the holding and the pigs contained therein, provided that the pigs in these units have been housed, kept and fed completely separately.

Article 9

1. Once the presence of swine fever is officially confirmed, the competent authority shall establish a protection zone with a minimum radius of 2 km around the infected holding.

2. a) The following measures shall apply to the protection zone :

   - the movement of pigs on public roads shall be prohibited;
   - the pigs may only be moved from the holding on which they are kept directl to a slaughterhouse under official supervision for the purpose of immediat slaughter. Such movement may be authorized by the competent authority onl after the official veterinarian has carried out an examination of all pigs on the holding and confirmed that none of the pigs is suspected of being infected with swine fever;
   - itinerant boar service shall be prohibited;

b) The measures applied in the protection zone shall be maintained until at least 15 days after the elimination of all pigs on the holding where there were pigs infected with swine fever and the completion of the cleaning and disinfection operations on that holding in accordance with the provisions of Article 10.

3. Where the prohibitions provided for in paragraph 2(a) are maintained beyond the 15 days prescribed because of the appearance of new cases of the disease and housing problems result, for the purposes of animal welfare the competent authority may, following an application by the owner stating the nature and extent of the problem, authorize the removal of piglets for fattening from a holding within the protection zone, provided that :

a) the official veterinarian has verified the facts;
b) the pigs have been examined and declared sound and are transported directly to the holding of destination without coming into contact with other animals, the means of transport used being cleaned and disinfected before and after use;
c) the holding of destination is located either in the protection zone or within 20 km of that zone and has adequate housing facilities;
d) the holding of destination is, upon arrival of the pigs, placed under official surveillance so that any suspicion of swine fever can be detected immediately, animals can be counted and their movements monitored.

The official surveillance measures provided for in d) shall be maintained for as long as those provided for in the protection zone in which the holding from which the pigs originated is located are maintained in accordance with paragraph 2(b).

4. Where the prohibitions provided for in paragraph 2(a) are maintained as a result of the derogation provided for in Article 6, the movement of animals other than directly to a slaughterhouse may be authorized subject to the following conditions :

- fattening pigs may be moved out of the zone provided that the official veterinarian is satisfied that there has been no contact with infected pigs and has examined them to rule out any suspicion of the disease;
- breeding pigs may be moved out of the zone provided that they have been examined by the official veterinarian and found free from all symptoms of the disease and that they have been examined for swine fever in accordance with Article 11 and the results were negative.

Article 10

The disinfectants to be used for the purposes of this Regulation and their concentrations shall be officially approved by the competent authority of the Member State concerned.

The cleaning and disinfection operations to be undertaken pursuant to this Regulation shall be carried out under official supervision, in accordance with the instructions given by the official veterinarian.

Article 11

1. Samples shall be taken, and the laboratory tests designed to detect the presence of classical swine fever carried out, in accordance with Annex I. The provisions of Annex I may be extended or amended in accordance with the procedure laid down in Article 16.

2. A national laboratory shall be responsible for coordinating standards and methods of diagnosis in each Member State in accordance with the provisions of Annex II.

3. A Community laboratory shall liaise between the national laboratories referred to in paragraph 2.

   The Council, acting on a proposal from the Commission, shall designate the Community laboratory and shall determine before .. its powers and the conditions of its operation.

Article 12

1. Without prejudice to Community provisions already existing on the subject, Member States shall inform the Commission and the other Member States about the epizootiology and development of the disease in accordance with the provisions set out in Annex III.

2. The provisions of Annex III may be extended or amended in accordance with the procedure laid down in Article 16.

Article 13

1. When pigs are moved from the holding on which they are kept, they must be provided with a mark enabling their holding of origin to be readily identified. The marking must be done in accordance with the instructions of the competent authority.

2. Persons engaged in the transport or sale of pigs must be in a position to supply the competent authority with information concerning the movements of pigs which they have transported or sold, and furnish proof of such movements. The same obligation shall be incumbent on all persons keeping pigs in respect of the pigs entering or leaving their holding.

Article 14

1. Where swine fever is detected on a holding, the measures to control the disease may be supplemented by the vaccination of pigs on holdings threatened with contamination in a territorial area demarcated by the competent authority.

2. Treatment with specific immune-serum or sero vaccination shall be prohibited.

3. Requirements relating to swine fever vaccine shall be adopted in accordance with the procedure laid down in Article 16.

4. Swine fever vaccines imported into a Member State from non-member countries must fulfil the same conditions as those produced in the Member States and must be authorized and controlled by the competent central authority in the importing Member State.

5. Without prejudice to national provisions where they provide for preventive vaccination of pigs against swine fever, whether in all or part of the national territory, where all categories of pigs are vaccinated pursuant to paragraph 1 sows vaccinated during gestation may leave the vaccinated area only to be taken to a slaughterhouse for slaughter.

6. The pigs vaccinated shall be permanently marked in accordance with the instructions of the competent authority.

Article 15

1. The use of swill originating from means of international transport such as boats, land vehicles or aircraft shall be prohibited for the feeding of pigs. Such swill must be collected and destroyed under official control.

2. Swill for the feeding of pigs must be heat-treated so as to ensure the destruction of swine fever virus. Swill so treated may be used for feeding to fattening pigs only.

3. The collection, transport and treatment of swill intended for feeding to pigs must be subject to official authorization. Swill must be transported in vehicles or containers designed in such a way that it cannot leak or fall out of the vehicle during transport.

   The vehicles or containers used for the transport of swill must be cleaned and disinfected each time after use according to the instructions of the competent authority.

4. The authorization for the treatment of swill referred to in paragraph 3 shall be granted subject to the following conditions :

   - the holding must have facilities which ensure that there is complete separation between untreated and treated swill;
   - the premises for storage of untreated swill and the premises where treatment takes place must be easy to clean and disinfect.

5. The swill collected in accordance with paragraph 3 may be used only on the holding where it has been treated.

   Member States may authorize the treatment of swill in special establishments equipped for the purpose, on which there are no animals and which are under official control. In this case, by way of derogation from paragraph 2, the swill may, after treatment, be used for the feeding of all categories of pigs, provided that its distribution and use are controlled so as to avoid all risks of the spread of swine fever virus.

6. The authorization referred to in paragraph 3 shall not be required in the case of holdings using their own swill for feeding to their own pigs, provided that such swill is heat-treated in a manner such as to ensure the destruction of swine fever virus.

Article 16

1. Where the procedure laid down in this Article is to be followed, the matter shall without delay be referred by the Chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter referred to as 'the Committee') set up by the Council Decision of 15 October 1968.

2. Within the Committee the votes of the Member States shall be weighted as laid down in Article 148 (2) of the Treaty. The Chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on these measures within a time limit set by the Chairman having regard to the urgency of the questions under examination. Opinions shall be delivered by a majority of 41 votes.

4. The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee. Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal on the measures to be taken. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within three months of the date on which the matter is referred to it, the Commission shall adopt the proposed measures and shall implement them immediately.

Article 17

Article 16 shall apply until 21 June 1981.

Article 18

This Regulation shall enter into force on 1 July 1980.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council

The President

ANNEX I

DIAGNOSTIC PROCEDURES FOR THE CONFIRMATION OF SWINE FEVER

The following guidelines, standards and minimum criteria are laid down for the diagnostic procedures. The designated National Swine Fever Laboratories shall define the materials and methods for use in the diagnosis of swine fever.

A. Collection of materials for diagnosis

1. For virus isolation and antigen detection, tonsil tissue is considered essential. Samples of kidney, spleen and ileum, together with maxillary and mesenteric lymph nodes should also be collected. Each sample of the tissue should be placed in a separate plastic bag and labelled. The samples should be transported and stored in leak proof containers. They should not be frozen but kept cool at refrigerator temperature and tested without delay.

2.a) Blood samples for virus isolation should be collected, preferably from pigs showing signs of fever or other signs of disease. Sterile non cytotoxic tubes should be used for this purpose, and the samples should be kept cool, preferably at refrigerator temperature and then subjected to laboratory testing without delay.

b) Blood samples may be collected for virus isolation from leucocytes of suspected pigs. Blood is prevented from clotting preferably by the addition of EDTA[1)]. The samples should be kept cool at refrigerator temperature and submitted to laboratory testing within two days.

3. Blood samples for the detection of antibody as an aid to diagnosis of clinical outbreaks and for the purposes of surveillance, should be taken from animals which have recovered from suspect infection and from sows known to have been in contact with infected or suspect cases. In such suspect holdings all suspect or in contact animals up to 20 and 25% of any additional number should be sampled. The samples should be collected and handled as described in paragraph 2(a).

(1) Ethylene Diamine Tetraacetic Acid, Sodium salt.

In order to ensure a high probability of detection of antibody induced by swine fever virus, samples should be collected from each unit of the holding at this level.

Sero diagnosis should not be attempted where vaccination has been officially carried out.

B. The laboratory diagnosis of swine fever

The principle basis for the laboratory diagnosis of swine fever shall be the demonstration of viral antigen in organ tissues as described in sub-paragraph 1.

In the case of negative or inconclusive results, the tests shall be repeated on the same samples. Additional samples should be collected from the same source.

Virus isolation is required in cases of inconclusive or negative results from material derived from animals giving rise to suspicion of swine fever or with material from holdings which have had contact with cases of swine fever. Where in such circumstances the demonstration of viral antigen or virus isolation has not been successful, tests for the detection of neutralizing antibody shall be applied to blood samples of animals which have recovered from the suspect disease and from those known to have been in contact with the disease.

Materials, methods and diagnostic criteria shall be prescribed by the National Swine Fever Laboratory in each Member State.

1. Demonstration of viral antigen

For the demonstration of viral antigen in organ tissues, the direct immunofluorescence technique shall be applied to thin cryostat sections (up to 5 microns) of tonsils and tissues of other organs as specified in paragraph A 1. For the application of the direct immunofluorescence test the following requirements shall be adopted :

a) Hyperimmune serum shall be prepared from pigs free from infections or antibody which could affect the specificity or quality of the reaction.

b) Fluorescein conjugated immunoglobulin prepared from swine fever hyperimmune pig serum as specified under a) shall have a minimum working titre of 1 : 20 as determined in swine fever infected cell cultures and confirmed by check tests on tissue sections. The working dilution of the conjugate shall combine a maximum of brilliance with a minimum of background staining.

c) Any sample showing specific cytoplasmic fluorescence shall be considered positive for swine fever. In case of doubt, the results should be confirmed by virus isolation in cell cultures.

d) When fluorescence has been detected which is suspected to be due to vaccinal virus, the holding shall be regarded as a suspect holding until such a time as the Competent Authority is satisfied that no swine fever exists on the holding.

2. Virus isolation and identification in cell cultures

a) Virus isolation from tissue samples is performed on susceptible [PK 15] cell cultures or equally susceptible cell lines. Cell cultures grown on coverslips are exposed to a suitably prepared 10% suspension of tissue from the suspected animal; starting with a 10% suspension, the cultures shall be stained and examined for specific cytoplasmic fluorescence at intervals from 24 to 72 hours from the time of inoculation.

b) Virus isolation from blood samples, collected and handles as indicated in paragraph A 2 b) is performed by the inoculation of cell cultures according to the procedures described in paragraphs A 2 a) or A 2 b) respectively. These cultures should be exposed to buffy coat suspension reconstituted to the original blood volume. In the case of serum samples the cell cultures should be exposed to not more than a 20% dilution of the serum to be tested.

C. Detection of antibody induced by swine fever virus in blood samples

The detection of neutralising antibody in blood samples is carried out to assist in the diagnosis of swine fever in holdings containing pigs showing clinical signs of the disease or in pigs believed to have had contact with infected pigs. It may also be carried out for the purposes of surveillance or for surveys in herds of unknown status.

For these purposes, blood samples should be collected according to the specifications in Paragraph A 2 a and subjected to an approved test.

The following tests based on the direct immunofluorescence technique are approved for use and must be carried out with the inclusion of appropriate positive and negative serum controls.

1. The Plaque Reduction Test (PRT)

This test is based on the microplaque counting method. Three-fold dilutions of serum commencing at 1 : 20 are tested against an equal volume of virus suspension containing 300 to 1,000 plaque forming units (PFU) of a virulent strain of swine fever virus using at least 2 monolayer cultures per dilution.

The results are expressed as the plaque reduction titre, which is the reciprocal of the serum dilution which reduces the number of fluorescent foci by 90% as compared with the 1 : 20 diluted negative control serum. The titres are determined graphically.

2. The Neutralisation Index Test (NI Test)

The test is based on the microplaque counting method. A stock of virus is titrated in cell cultures in the presence of an equal volume of a 1 : 20 dilution of serum. At least two monolayer cultures are required for each $\log_{10}$ dilution of virus suspension.

The degree of neutralising activity is expressed as the difference between the infectious titre in the presence of a 1 : 20 dilution of known negative serum and the titre of the same virus suspension in the presence of the suspect serum.

This difference is the Neutralisation Index and is expressed logarithmically.

3. The virus neutralization and immunofluorescence test (NIFT)

This test is based on the determination of the fifty percent end point. Cultures are inoculated with constant amounts of virus after incubation with serum and the results are based on the absence of any specific cytoplasmic fluorescence.

The sera are diluted 1 : 5 for screening purposes. Two fold dilutions of serum starting at 1 : 5 are prepared when a full titration is necessary. Each dilution is mixed with an equal volume of virus suspension containing 100 to 200 infectious doses ($TCID_{50}$). At least two cultures are used at each dilution level. The NIFT results are expressed as the reciprocal of the dilution at which half the inoculated cell cultures fail to show any specific fluorescence. An end-point between two dilution levels is interpolated.

D. Evaluation of the results of laboratory testing

1. The demonstration of viral antigen in organ tissues or virus isolation from tissue samples following the techniques defined in paragraphs B 1 and B 2 shall form the basis of confirmation of the presence of the disease except in the case of a reaction demonstrated to be due to vaccinal virus according to paragraph B 1 d).

2. Following the detection of antibody reacting with swine fever virus, the herd of origin shall be regarded as suspect.

   a) In order to rule out the suspicion of swine fever raised by the detection of antibody, the test described in Section E below shall be used to distinguish between swine fever reacting antibody that may have been induced by BVD virus and such antibody due to swine fever virus itself. All original samples shall be retested by the differential test.

   b) If suspicion cannot be ruled out on the first differential test, a further test carried out at least 30 days later to follow up the possible spread of infection. All of the first 20 animals on the suspect holding shall be sampled and 25% of any additional animals.

3. Interpretation of serological results

   (a) Plaque Reduction Test (PRT)

   A titre of $\geqslant$ 50 in any pig together with clinical or epizootiological evidence giving rise to suspicion of disease shall constitute a positive diganosis.

   A titre of $\geqslant$ 50 in any pig without clinical or epizootiological evidence gives rise to suspicion of disease and should be followed by differential diagnostic procedures.

   (b) Neutralization Index (NI)

   A titre of $\geqslant$ 1.0 in any pig together with clinical or epizootiological evidence giving rise to suspicion of disease shall constitute a positive diagnosis.

   A titre of $\geqslant$ 1.0 in any pig without clinical or epizootiological evidence gives rise to suspicion of disease and should be followed by differential diagnostic procedures.

   (c) Virus Neutralization and immunofluorescence test (NIFT)

   A titre of $\geqslant$ 5 in any pig together with clinical or epizootiological evidence giving rise to suspicion of disease shall constitute a positive diagnosis.

   A titre of $\geqslant$ 5 in any pig without clinical or epizootiological evidence gives rise to suspicion of disease and should be followed by differential diagnostic procedures.

E. Differential diagnosis between swine fever (SF) and bovine virus diarrhoea (BVD)

1. Tests for the differential diagnosis of swine fever (SF) and bovine virus diarrhoea (BVD) are based on parallel end-point titrations of the sera with both SF and BVD virus strains using fully comparable methods. The SF and BVD virus strains for use should be approved by the National Swine Fever Laboratory.

   To rule out the suspicion of swine fever raised by the detection of antibody blood samples should be examined by comparative end-point titrations for neutralising antibody against SF-virus and BVD-virus.

2. The results of the comparative serological tests between swine fever and bovine virus diarrhoea shall be interpreted as follows :

   a) If the comparative tests show :
      - that more than one pig has antibody to SF with no antibody to BVD, or
      - that the titres against SF-virus are equal to or higher than the titres against BVD in a large proportion of the pigs, swine fever shall be confirmed.

   b) If the comparative tests show some of the titres to SF-virus to be equal to or higher than the titres to BVD-virus in a proportion of the pigs there shall be suspicion of swine fever and differentiation shall proceed as follows :
      - those pigs which show neutralizing titres against SF-virus which are higher than or equal to the titres against BVD-virus shall be slaughtered and their foetuses together with any tissues estimated to be of value shall be subjected to examination for swine fever antigen or virus.
      - if swine fever antigen or virus is detected, swine fever shall be confirmed.
      - if the examination defined in the second indent above fails to reveal the presence of swine fever antigen or virus, the holding shall be considered as suspect until a further set of blood samples collected at least 30 days later has been subjected to further comparative tests.
      - if these subsequent comparative tests show all animals to have significantly (four-fold or greater) higher titres against BVD-virus than SF-virus, suspicion shall be ruled out.
      - if one or more animals show a titre against SF virus that is equal to or higher than its titre to BVD-virus, swine fever shall be confirmed.

   c) If the BVD titres are such as not to exclude the possibility of swine fever, the holding shall be considered as suspect and be retested after at least 30 days.

ANNEX II

The national swine fever laboratories are as follows :

Denmark	National Virus Research Institute, Lindholm
Italy	Istituto zooprofilattico sperimentale dell'Umbria e delle Marche - Perugia
Great Britain	Central Veterinary Laboratory Weybridge - Surrey - England
Northern Ireland	Veterinary research laboratory Stormont - Belfast
Belgium	Institut national de recherches vétérinaires Groeselenberg 99 Bruxelles B 1180
France	Laboratoire central de Recherches vétérinaires d'Alfort, Rue Pierre Curie 22, 94700 Maisons Alfort
Luxembourg	Laboratoire bactériologique de médecine vétérinaire de l'Etat; Avenue Gaston Diderich 54, Luxemburg
Ireland	Veterinary research laboratory Abbotstown - Castleknock - Co. Dublin
Germany	Bundesforschungsanstalt für Viruskrankheiten der Tiere, Tübingen
Netherlands	Central veterinary Institute - Lelystad

The national swine fever laboratory in each Member State shall be responsible for coordinating the standards and diagnostic methods laid down in each swine fever diagnostic laboratory within the Member State, by :

(a) providing diagnostic reagents to individual laboratories where required;

(b) controlling the quality of all diagnostic reagents used in that Member State;

(c) arranging comparative tests periodically;

(d) holding isolates of swine fever virus from cases confirmed in that Member State.

ANNEX III

Epizootiologic information

1. Within 24 hours of notification of an outbreak of swine fever, the Member State concerned must forward the following information to the Commission and the other Member States :

   - the date on which swine fever was suspected;
   - the date on which swine fever was confirmed and methods used for confirmation;
   - the location of the infected holding and its distance from the nearest pig farms;
   - the number of pigs of each category on the holding;
   - for each category, the number of pigs in which swine fever has been confirmed and the morbidity of the disease.

2. The information specified in paragraph 1 shall be followed as soon as possible by a report stating the following :

   - the date on which the pigs on the holding were slaughtered and destroyed;
   - where the derogation provided for in Article 6 has been applied, the number of pigs slaughtered and destroyed and the number of pigs which are to be slaughtered at a later date and the time limit laid down for their slaughter;
   - any information relating to the possible origin of the disease, or the origin of the disease if this has been ascertained.

3. The Member State concerned shall forward the information specified in paragraph 1 to the Commission and the other Member States in respect of each subsequent outbreak of swine fever on other holdings, until the number of infected holdings and the dispersion of the disease show the epizootic to be extensive.